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08/199,070 02/22/94 MARASCO

W 43471

EXAMINER

CAMPBELL, B

ART UNIT

PAPER NUMBER

18M1/0319

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DIKE, BRONSTEIN, ROBERTS & CUSHMAN
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BOSTON, MA 02109-4280

1804

DATE MAILED:

03/19/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11/13/93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.. 6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 3-16 are pending in the application.
- Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 2 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 3-16 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☒ The proposed additional or substitute sheet(s) of drawings, filed on 11/13/95, has (have) been ☒ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

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PTOL-326 (Rev. 2/93)

EXAMINER'S ACTION

The amendment filed November 13, 1995 has been entered.

On further consideration, the restriction requirement (paper 5) is withdrawn. Since the specification is enabling for *in vivo* methods it is clearly enabling for *in vitro* methods, and the same prior art applies to either type of method.

Claims 1, 3-9 and 13-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 is indefinite and confusing in its recitation of "antibody targeting moiety", which literally means a moiety which targets an antibody.

Claim 6 remains indefinite because some of the recited proteins are actually protein families. Applicants argue that the use of non-equivalent species in the Markush group is not indefinite because it is "clear" that recitation of a protein family means all members of the family. This argument is not persuasive because Applicants have not pointed out where in the specification this is made clear.

Claim 9 is indefinite and confusing because it contains an unpaired bracket ("]").

Claims 13, 15 and 16 remain vague and indefinite in their recitation of "waiting until..." because it is not clear how long one should wait for the recited event to occur, nor how the event is detected.

Claims 15 and 16 remain indefinite because it is not clear what the purposes of the methods are.

Claims 15 and 16 remain incomplete because they do not recite a step in which the nucleic acid is delivered into the target cell.

Applicants argue that those skilled in the art would understand these claims. This argument is not persuasive. The preamble is indefinite because it does not clearly set forth what the method is intended to accomplish.

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"Waiting" is not in itself a positive process step, and there is no final step to accomplish any stated purpose. Definite claim language is suggested below:

--A method for transfecting a cell with a nucleic acid, comprising contacting the cell with the nucleic acid delivery system of claim 1, whereby the cell is transfected with the nucleic acid.--

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1, 3-5 and 7-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Beug et al. in view of Chaudhary et al. and Wu et al. as previously stated for claims 2-5, 7 and 10-16 (paper 7, pp. 6-8).

Claim 6 is rejected under 35 U.S.C. § 103 as being unpatentable over Beug et al. in view of Chaudhary et al. and Wu et al. as applied to claims 1, 3-5, and 7-16 above, and further in view of Ryder et al., as previously stated (paper 7, p. 8).

Applicants traverse the above two rejections on the same grounds, so they will be treated together.

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Applicants argue that Beug et al. do not teach making a fusion protein. This is incorrect, since Beug et al. explicitly suggest producing their compositions as fusion proteins and indicate that this method has advantages over chemical conjugation (p. 8).

Applicants argue that there was no suggestion to use an antibody as a targeting moiety. This is incorrect, since Wu et al. state that "other ligands such as antibodies...also may be employed" (col. 6).

Applicants again argue that the desirability of using a fusion protein was not taught. As noted above, this is incorrect because Beug et al. specifically point out the advantages of this method.

Applicants argue that the rejection uses hindsight. This argument is not persuasive because Applicants have not pointed out any aspect of the claimed invention that was not known in the prior art, nor any reason why one of ordinary skill in the art would not have thought to combine the teachings of the references, nor any reason why the results obtained by Applicants would not have been expected by one of ordinary skill in the art.

Applicants argue that there is no "blueprint" for the invention in any of the references. Applicants are reminded that if there were such a blueprint, the claims would be anticipated under § 102. "The test for obviousness is not...that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the of the references would have suggested to those of ordinary skill in the art." (*In re Keller, Terry, and Davies*, 208 USPQ 871 at 881) Wu et al. and Beug et al. each disclose the general concept of receptor-mediated transfection. Beug et al. teach the desirability of using a fusion protein. Wu et al. suggest using an antibody to target particular cells, and Chaudhary et al. disclose an antibody which effectively targets a macromolecule (protein) to the desired cell type. Thus all elements of the invention were known in the art, and there were explicit suggestions to combine these

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elements. Thus the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).


A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce Campell, whose telephone number is 703-308-4205. The examiner can normally be reached on Monday-Thursday from 8:30 to 5:00 (Eastern time). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone, can be reached on 703-308-3153. The FAX phone number for art unit 1804 is 703-308-0294.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Bruce Campell
March 15, 1996


BRUCE A. CAMPBELL
PATENT EXAMINER
GROUP 1800